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Kathy Honnert

Docket No. 0008.15

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Robert M. PLATZ *et al.*

Examiner: Mina HAGHIGHATIAN

Serial No.: 10/072,430

Art Unit: 1616

Filed: February 8, 2002

Title: **COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF AEROSOLIZED MEDICAMENTS**

#3
Khanna
12/16/02

REPLY UNDER 35 U.S.C. §1.111

Assistant Commissioner
for Patents
Washington, D.C. 20231

Sir:

This reply is in response to the Office Action mailed October 2, 2002, received in connection with the above-identified patent application. As this response is being filed within the three-month shortened statutory period, no extension fees are due.

REMARKS

I. Introductory Comments

In the Office Action under reply, the claims were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hanes *et al.* (U.S. Patent No. 5,855,913) (claims 1, 3-5, 12-18, 20 and 22-25). In addition, claims 1-25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the claims of

copending application No. 09/616,236 in view of Snyder *et al.* (U.S. Patent Application Publication US2002/0071871). The rejections are addressed as indicated below.

Claims 1-25 are pending in the application. No claims have been deleted or amended. Consequently, claims 1-25 remain pending.

II. The Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1, 3-5, 12-18, 20 and 22-25 under 35 U.S.C. §103(a) as allegedly being unpatentable over Hanes *et al.* (U.S. Patent No. 5,855,913). Although it is Applicants' position that the present claims are patentable over Hanes *et al.*, Applicants traverse the rejection on the ground that Hanes *et al.* does not represent prior art to the present application and therefore cannot form the basis of rejecting claims 1, 3-5, 12-18, 20 and 22-25 under 35 U.S.C. §103(a).

In order for a reference to be cited in a rejection based on 35 U.S.C. §103(a), the reference must represent prior art to the pending application. Consequently, a comparison is made between the effective date of reference and the effective date of the pending application and only those references having an effective date earlier than the pending application will qualify as prior art.

Initially, the effective date of Hanes *et al.* must be established. As stated in section 2136.03 of the Manual of Patent Examining Procedures (M.P.E.P.), a U.S. patent is effective prior art as of its U.S. filing date. Here, the application corresponding to Hanes *et al.*'s patent was filed on January 16, 1997 (without claiming priority to any other application). Thus, the effective prior art date of Hanes *et al.* is January 16, 1997.

Having established the effective prior art date of Hanes *et al.*, it is now necessary to determine the effective date of the present application. "[T]he effective filing date is the same as the earliest filing date in the line of continuation or divisional applications." M.P.E.P. §706.02. As indicated on the Utility Patent Application Transmittal form, the present application is, *inter alia*, a continuation of U.S. Patent Serial No. 08/423,515, which was filed on April 14, 1995 (still pending). Consequently, the present application is entitled to an effective filing date of at least as early as April 14, 1995.

It must be stressed, however, that the present application may be entitled to an even earlier filing date than April 14, 1995 given the claims of priority to other applications filed

earlier than April 14, 1995. For expediency purposes only, however, Applicants rely on the priority claim to U.S. Patent Application Serial No. 08/423,515. Applicants nevertheless reserve the right to argue that the present application is entitled to an effective filing date earlier than April 14, 1995.

Having established January 16, 1997 as the effective prior art date of Hanes *et al.* and at least as early as April 14, 1995 as the effective filing date of the present application, it is clear that Hanes *et al.* does not represent prior art to the present application. Without the disclosure of Hanes *et al.*, the Examiner's obviousness rejection cannot stand as no other prior art reference is cited. Again, although it is Applicants' position that the claims are patentable over Hanes *et al.*, the argument that Hanes *et al.* does not represent prior art to the present application is considered sufficient for withdrawal of the rejection.

Of course, if the Examiner is of the opinion that Hanes *et al.* in some way represents prior art to the present application (e.g., by an imperfect claim of priority to U.S. Patent Application Serial No. 08/423,515), Applicants request the Examiner to set forth the basis of her position. Although Applicants do not believe such a basis exists, Applicants reserve the right to rebut the Examiner's position and/or otherwise correct any alleged deficiency (e.g., by perfecting a priority claim).

II. The Double Patenting Rejection

Claims 1-25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the claims of copending application No. 09/616,236 in view of Snyder *et al.* (U.S. Patent Application Publication US2002/0071871).

To obviate this rejection, an executed terminal disclaimer is enclosed herewith. In view thereof, it is submitted that the nonstatutory double patenting rejection of the present claims is overcome. Applicants note that submission of the terminal disclaimer is for expediency purposes only and is not intended as an acquiescence in the rejection.

IV. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all

rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
Inhale Therapeutic Systems, Inc.

Date: November 13, 2002

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